TRULINCS 48860039 - FATA, FARID - Unit: WIL-A-B

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FROM: 48860039
TO:
SUBJECT: JUDICIAL NOTICE TO THE COURT
DATE: 10/18/2021 06:48:34 AM

CASE No: 2:13-cr-20600

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA Plaintiff,	)	
v.	)	Hon. Paul D. Borman
FARID FATA Defendant.	)	

JUDICIAL NOTICE TO THE COURT

Defendant Farid Fata ("Fata") respectfully submits this Judicial Notice, to notify the Court of the following new developments with medical records and prison documents related to Fata's health care involved in Fata's Renewed Motion for Compassionate Release pursuant to 18 U.S.C. 3582(C)(1)(A).

I - FATA DEVELOPED NEW URINARY TRACT INFECTION WITH PROSTATITIS AS COMPONENT OF HIS IMMUNOCOMPROMISED NEUTROPENIC STATUS WHILE HIS CARE CANNOT BE MET IN BOP CUSTODY:

In his Memorandum Supplemental Brief filed on July 26, 2021 (DE # 345), Fata has shown that since after he contracted COVID-19 in prison with long hauler syndrome, Fata's systemic neutropenic recurrent infections involved multiple organs including the respiratory tract (COVID-19), skin (Bacterial infection on 4-27-2021, and fungal on 7-9-2021), gums (6-30-2021), and gastrointestinal tract (colon periapical abscess found on colonoscopy), that place Fata at substantial risk to develop COVID-19 vaccine breakthrough infection with severe illness and death as the CDC reported that "40% of vaccinated patients who are hospitalized with breakthrough COVID infections are immunocompromised". To date, the government took no position on the impact of Fata's overlapping medical conditions with systemic recurrent infections that are caused by Fata's immunocompromised neutropenic status. United States v. Newton, 996 F.3d 485; No. 20-2893, (7th Cir. May 4, 2021)(the Seventh remanded and noted that if "the district court treats all of Newton's medical conditions as ones that put him at increased risk for reinfection, it should find him eligible for release". (emphasis added)).

On October 8, 2021, Fata was diagnosed with urinary tract infection manifested with prostatitis (infection of the prostate causing urinary burning for 4 weeks, frequent urination for 4 months, and pelvic pain) (Exhibit A), confirmed on urinalysis (Exhibit B) and required prolonged antibiotic treatment with ciprofloxacin for two weeks (Exhibit C). United States v. Wardlow, No. 2:19-cr-20254, 2021 U.S. LEXIS 81161, at *9 (E.D. Mich. Apr. 28, 2021)(finding extraordinary and

compelling circumstances and granting motion, in part based on medical {2021 U.S. Dist. LEXIS 8} conditions, despite having likely received two vaccine doses). See also United States v. Sherrod, 2021 U.S. Dist. LEXIS 147643, Case No. 19-20139 (E.D. Mich. Aug. 6, 2021)(the Court noted that "even those court decisions denying release based on full vaccination status have noted that their calculus might change if there were a shift in the scientific consensus. It appears that the proliferation of COVID-19 variants has begun to usher in such a shift". The Court finds that despite vaccination, Sherrod's heightened susceptibility to severe illness from COVID-19 ... with no criminal history and a spotless record in prison satisfies the extraordinary and compelling reasons for release. Sherrod served 30% of his sentence). The Sherrod Court was referring to the CDC REDCap database that continues to report exponential increase in COVID-19 vaccine breakthrough infections with hospitalization and death (Exhibit D).

Although the FDA label of ciprofloxacin recommends that the duration of antibiotic treatment for chronic prostatitis is 28 days that controls the infection in 40% to 75% of the cases (Exhibit E), the Bureau physician knowingly prescribed 14-day half course of antibiotic breaching the standard of care which can render the infection incurable with increased short and long term complications of recurrent prostatitis, chronic pelvic pain syndrome, erectile dysfunction, and prostate cancer (Exhibit F, Second Opinion). By prescribing ciprofloxacin for a duration of 14 days instead of the standard 28 days, the provider caused early interruption of Fata's treatment putting Fata at future health risk. Boretti v. Wiscomg, 930 F. 2d 1150 (6th Cir. 1991)(A nurse's interruption of standard treatment constituted deliberate indifference, despite the fact that the inmate's wound eventually healed); See also Helling v. McKinney, 509 U.S. 25 (1993)(Supreme Court case on future health risk).

In Fata's case, the current issue is not about a "doctor's professional judgment" or "disagreement about treatment choice" nor "negligence or incompetence about duration of treatment" as the Bureau provider told Fata during the October 8, 2021 encounter that he should receive 28 days of antibiotic, but the provider knowingly chose to prescribe half course because pharmacy would only dispense 14-day treatment course (Exhibit G). The provider was aware of the consequences and complications associated with a short antibiotic treatment, and failed to respond to Fata's emails. i.e. He failed to respond to Fata's health risk (Exhibit H). Instead, the provider could and should have submitted for the complete 28-day course of antibiotic for Region to approve, but he chose an easier and less effective treatment plan as he followed FCI Williamsburg's pharmacy practices that have no knowledge to manage Fata's clinical condition whatsoever, absent established clinical pathways within the BOP to treat chronic prostatitis. Pharmacy has no justification or clinical data to support a short incomplete course of antibiotic. Fata's prostatitis presents a serious medical need for the Eighth Amendment purposes as it caused Fata to suffer pelvic pain, urinary burning, and frequent urination with noctiuria. Bertl v. City of Westland, 2009

U.S. App. LEXIS 2086 (6th Cir. Feb. 2, 2009); Farmer v. Brennan, 511 U.S. 825, 837-38, 114 S. Ct. 1970, 128 L. Ed. 2d 811 (1994)(deliberate indifference). The Provider knew of the risk to Fata's health, and failed to respond to the risk and prevent harm by disregarding that risk through failing to verify and address the existing facts given to him in Fata's emails (Exhibit H).

To close on a different matter, as of the date of this notice, Fata has not yet seen the dentist since he was told to watch for callout on June 1, 2021 (DE # 345), nor have the CT Scan of the head (work-up of headaches as component of Long Covid), and the Nerve Conduction Studies (NCS) been performed since his clinical encounter on March 26, 2021 (DE # 319) .

II - FATA RECEIVES PROMOTION AT UNICOR INDUSTRIALS:

On October 4, 2021, Fata received a higher rank promotion at Unicor Industrials pursuant to his remarkable performance and good conduct (Exhibit I) despite suffering the lingering long COVID symptoms at work (Exhibit A). United States v. Williams, 2021 U.S. App. LEXIS 9574. No. 20-2133, (6th Cir. Apr. 1, 2021)(the Sixth Circuit remanded as "the district court did not explain why Williams' post-conviction rehabilitation was not entitled to more weight in its evaluation of the sentencing factors).

III - FCI WILLIAMSBURG OPERATES AT THE HIGHEST COVID-19 LEVEL 3 OPERATIONS INTENSE MODIFICATIONS :

Due to the local community COVID-19 rates, lagging vaccinations in the community at large, and the presence of new active COVID-19 cases involving staff and inmates, FCI Williamsburg is operating at "level 3 operations Intense Modifications" (Exhibit J). Nearly 35% of inmates at FCI Williamsburg remain unvaccinated and more likely to transmit the virus. https://www.bop.gov/coronavirus/[https://perma.cc/ZN7K-YFBX]

IV - FATA REQUESTED THE PFIZER BOOSTER THIRD DOSE THOUGH HIS ANTIBODY RESPONSE BENEFIT IS LOW :

On August 13, 2021, the FDA authorized and the CDC recommended a booster third dose of Pfizer and Moderna COVID-19 vaccines in patients with moderately to severely impaired immune function (Exhibit K).

Based on Fata's personal history of neutropenic recurrent infections, Fata's immunocompromised status is considered at least moderate. Therefore, Fata should receive the Pfizer booster dose, even knowing that only 30%-40% of immuno-compromised patients who did not develop antibodies after two doses of the vaccine benefit from the booster with some level of protection after a third dose (Exhibit K). i.e. the danger is not over for Fata as he has a 60%-70% risk not to develop antibodies after the third dose and as the CDC reported that 40% of vaccinated patients who are hospitalized with breakthrough infections are immunocompromised (Exhibit K).

Until FCI Williamsburg health services receive guidance from the BOP, Fata asked the Bureau provider to order antibody testing (Exhibit L) to determine whether Fata had developed immune response to the Pfizer vaccine

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as a marker authorized by the FDA and recommended by the CDC to prescribe a booster dose in the immunocompromised. Fata's request was denied (Exhibit L).

As the CDC's ACIP (Advisory Committee on Immunization Practices) member Helen Talbot, MD, MPH, stated:

"My only concern with adding a third dose for the immunocompromised is the impression that our immunocompromised population [will] then be safe" ... "but still at incredibly high risk for severe illness and death" (Exhibit K).

V - CONCLUSION:

Fata urges this Court to unleash its discretion and release him to a safe environment confined at his release residence to mitigate his risk for recurrent infections (COVID-19 and others) that caused him substantial pain and suffering. United States v. Fields. No. 12-cr-20274. U.S. Dist. LEXIS 229692, (E.D. Mich. Dec. 8, 2020); see also United States v. Spencer, No. 20-3721, 2020 U.S. App. LEXIS 28051 (6th Cir. Sept. 2, 2020)(The Sixth Circuit noted that "the District Court may reduce a defendant's sentence under 3582(C)(1)(A) to time served and then impose a term of supervised release, including a period of house confinement equal to the remainder of the original prison term, if it finds that the defendant meets the criteria set forth in 3582(C)(1)(A)").

Respectfully Submitted,

Farid Fata

October 18, 2021

Farid Fata
48860-039
FCI Williamsburg
P.O. Box 340
Salters, SC 29590

TRULINCS 48860039 - FATA, FARID - Unit: WIL-A-B

FROM: 48860039
TO:
SUBJECT: MOTION TO SEAL EXHIBITS
DATE: 10/18/2021 06:48:57 AM

CASE No. 2:13-cr-20600

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA Plaintiff,	)	
v.	)	Hon. Paul D. Borman
FARID FATA Defendant.	)	

MOTION TO SEAL EXHIBITS

Defendant Farid Fata moves to request that the Court grants his Motion to seal the Exhibits of his Judicial Notice related to his Renewed Motion for Reduction of sentence Pursuant to 18 U.S.C. 3582(C)(1)(A) as the exhibits contain sensitive medical records and personal information.

Respectfully Submitted,

Farid Fata October 18, 2021
48860-039
FCI Williamsburg,
P.O. Box 340
Salters, SC 29590

EXHIBIT A

Bureau of Prisons
Health Services
Clinical Encounter

Inmate Name: FATA, FARID			Reg #: 48860-039
Date of Birth: 04/09/1965	Sex: M	Race: WHITE	Facility: WIL
Encounter Date: 10/08/2021 10:54	Provider: Dominici, Raymond MD		Unit: A04

Chronic Care - Chronic Care Clinic encounter performed at Health Services.

SUBJECTIVE:

COMPLAINT 1 Provider: Dominici, Raymond MD

Chief Complaint: Chronic Care Clinic

Subjective: 56 year old male seen during COVID-19 RESTRICTIONS AND MODIFIED OPERATIONS PLAN.
He has a PMH of DMII and neuropathy of feet, hyperlipidemia, mild neutropenia and confirmed COVID-19 in 2020. For the past 3-4 weeks he reported that his urine has a bad odor and he has discomfort with sitting. He denied a h/o prostatitis or kidney stones, but he reported that he has had nocturia of approx 6x/night for the past 6 months. He reported that his neuropathy of his feet is worsening despite HgA1c less than 6 since 2016. He also reported that he has had several symptoms since he had COVID-19 in Dec 2020, including fatigue, daytime somnolence and poor memory. He reported that some days are worse than others. All chronic care clinic issues were discussed at length. Previous labs and records were reviewed. Patient appears to be doing fairly well clinically. Medications were reviewed and discussed. Patient reported compliance with medication. Plan of therapy was discussed with the patient. Appropriate counseling about medications, exercise/activity, diet and recommended follow-up were also given to the patient.

Pain: Yes

Pain Assessment

Date:	10/08/2021 11:30
Location:	Scrotum
Quality of Pain:	Aching
Pain Scale:	5
Intervention:	antibiotic
Trauma Date/Year:	
Injury:	
Mechanism:	
Onset:	3-4 Weeks
Duration:	12-24 Hours
Exacerbating Factors:	sitting
Relieving Factors:	standing
Reason Not Done:	
Comments:	

Seen for clinic(s): Diabetes, Endocrine/Lipid, Gastrointestinal, General, Orthopedic/Rheumatology

ROS:

General

Constitutional Symptoms

Yes: Fatigue

No: Chills, Fever, Unexplained Weight Loss

HEENT

Head

No: Headaches

Cardiovascular

General

No: Angina, Edema, Exertional dyspnea, Orthopnea

Pulmonary

Respiratory System

No: Cough - Dry, Cough - Productive, Shortness of breath, Wheezing

GI

General

No: Abdominal Pain or Colic, Blood in Stools, Constipation, Nausea, Vomiting

GU

General

Yes: Dysuria, Hematuria (Duration: a few times over the last few days), Nocturia

No: Hx Kidney Stones, Urinary Retention

Musculoskeletal

General

No: Joint pain

Neurological

Cranial Nerves

Yes: Within Normal Limits

No: Difficulties in Speech/Swallowing/Taste

Motor System

No: Weakness

Sensory System

Yes: Paresthesia

Endocrine

General

No: Polydipsia

Psychiatric

General

Yes: Memory Impaired

No: Mood-Down, Anxious, Hallucinations-Auditory, Hallucinations-Visual, Suicide/Self-Harm Thoughts, Homicide/Other Harm Thoughts

OBJECTIVE:

Temperature:

Date	Time	Fahrenheit	Celsius	Location	Provider
10/12/2021	00:29 WIL	97.9	36.6		Dominici, Raymond MD

Pulse:

Date	Time	Rate Per Minute	Location	Rhythm	Provider
10/12/2021	00:29 WIL	78		Regular	Dominici, Raymond MD

Respirations:

Date	Time	Rate Per Minute	Provider
10/12/2021	00:29 WIL	14	Dominici, Raymond MD

Inmate Name: FATA, FARID
Date of Birth: 04/09/1965
Encounter Date: 10/08/2021 10:54
Sex: M Race: WHITE
Provider: Dominici, Raymond MD
Reg #: 48860-039
Facility: WIL
Unit: A04

Date	Time	Rate Per Minute	Provider

Blood Pressure:

Date	Time	Value	Location	Position	Cuff Size	Provider
10/12/2021	00:29 WIL	119/79				Dominici, Raymond MD

SaO2:

Date	Time	Value(%)	Air	Provider
10/12/2021	00:29 WIL	99		Dominici, Raymond MD

Weight:

Date	Time	Lbs	Kg	Waist Circum.	Provider
10/12/2021	00:29 WIL	164.0	74.4		Dominici, Raymond MD

Exam:

General

Affect

Yes: Cooperative

Appearance

Yes: Appears Well, Alert and Oriented x 3

Head

General

Yes: Symmetry of Motor Function, Atraumatic/Normocephalic

Eyes

General

Yes: PERRLA, Extraocular Movements Intact

Pulmonary

Auscultation

Yes: Clear to Auscultation

No: Crackles, Rhonchi, Wheezing

Cardiovascular

Auscultation

Yes: Regular Rate and Rhythm (RRR), Normal S1 and S2

No: M/R/G

Vascular

Yes: Carotid Bruits

Peripheral Vascular

General

No: Pitting Edema

Abdomen

Auscultation

Yes: Normo-Active Bowel Sounds

Palpation

Yes: Soft

No: Tenderness on Palpation, Mass(es)

Neurologic

Cranial Nerves (CN)

Yes: CN 2-12 Intact Grossly

Motor System-Strength

No: Weakness

Exam Comments

Musculoskeletal
Yes: Grossly normal, ambulating easily without assistance

Comments

DUE TO COVID-19 Restrictions, Peak Flow testing was not performed.

ASSESSMENT:

Diabetes mellitus, type II (adult-onset), 250.00 - Current

Other and unspecified hyperlipidemia, 272.4 - Current

Disorder of prostate, unspecified, N429 - Current - *prostatitis and bph*

Neuralgia and neuritis, unspecified, M792 - Current

Neutropenia, unspecified, D709 - Current

Rash and other nonspecific skin eruption, R21 - Resolved

PLAN:

New Medication Orders:

Rx#	Medication	Order Date
	Tamsulosin HCl Capsule	10/08/2021 10:54
	Prescriber Order: 0.4mg Orally - daily x 365 day(s)	
	Indication: Disorder of prostate, unspecified	

Renew Medication Orders:

Rx#	Medication	Order Date
153412-WIL	Atorvastatin 20 MG TAB	10/08/2021 10:54
	Prescriber Order: Take one tablet by mouth at bedtime for control of cholesterol x 365 day(s)	
	Indication: Other and unspecified hyperlipidemia	
153413-WIL	metFORMIN HCl 500 MG Tab	10/08/2021 10:54
	Prescriber Order: Take one tablet (500 MG) by mouth twice daily x 365 day(s)	
	Indication: Diabetes mellitus, type II (adult-onset)	

Schedule:

Activity	Date Scheduled	Scheduled Provider
Chronic Care Visit DM, E/I, GI, Gen, O/R	10/07/2022 00:00	Physician 02

Disposition:

Follow-up at Sick Call as Needed

Other:

Follow up with Chronic Care Clinic(s) as instructed

Patient Education Topics:

Date Initiated	Format	Handout/Topic	Provider	Outcome

Inmate Name: FATA, FARID
Date of Birth: 04/09/1965
Encounter Date: 10/08/2021 10:54
Sex: M Race: WHITE
Provider: Dominici, Raymond MD
Reg #: 48860-039
Facility: WIL
Unit: A04

Date Initiated	Format	Handout/Topic	Provider	Outcome
10/12/2021	Counseling	Compliance - Treatment	Dominici, Raymond	Verbalizes Understanding
10/12/2021	Counseling	Compliance - Treatment	Dominici, Raymond	Verbalizes Understanding

Copay Required: No **Cosign Required:** No

Telephone/Verbal Order: No

Completed by Dominici, Raymond MD on 10/12/2021 00:51

Bureau of Prisons
Health Services
Clinical Encounter - Administrative Note

Inmate Name:	FATA, FARID			Reg #:	48860-039
Date of Birth:	04/09/1965	Sex:	M Race:WHITE	Facility:	WIL
Note Date:	10/08/2021 10:31	Provider:	Dominici, Raymond MD	Unit:	A04

Admin Note - Orders encounter performed at Health Services.

Administrative Notes:

ADMINISTRATIVE NOTE **1** Provider: Dominici, Raymond MD

Orders ahead of note

ASSESSMENTS:

Disorder of prostate, unspecified, N429 - Current

New Medication Orders:

Rx#	Medication	Order Date
	Ciprofloxacin Tablet	10/08/2021 10:31

Prescriber Order: 500mg Orally - Two Times a Day x 14 day(s)

Indication: Disorder of prostate, unspecified

Start Now: Yes

Night Stock Rx#:

Source: Sub Stock Location

Admin Method: Self Administration

Stop Date: 10/22/2021 10:30

MAR Label: 500mg Orally - Two Times a Day x 14 day(s)

One Time Dose Given: No

Copay Required: No **Cosign Required:** No

Telephone/Verbal Order: No

Completed by Dominici, Raymond MD on 10/08/2021 10:37

EXHIBIT B

Bureau of Prisons
Health Services
Clinical Encounter - Administrative Note

Inmate Name:	FATA, FARID			Reg #:	48860-039
Date of Birth:	04/09/1965	Sex:	M Race: WHITE	Facility:	WIL
Note Date:	10/08/2021 12:25	Provider:	Dominici, Raymond MD	Unit:	A04

Review Note - Report Review encounter performed at Health Services.

Administrative Notes:

ADMINISTRATIVE NOTE 1 Provider: Dominici, Raymond MD

Clinical symptoms of prostatitis with UA findings of blood and LE.
Started antibiotics. No fever. Will follow.

New Non-Medication Orders:

Order	Frequency	Duration	Details	Ordered By
Urine Dipstick	One Time		due Dec 2021	Dominici, Raymond MD

Order Date: 10/08/2021

Copay Required: No **Cosign Required:** No

Telephone/Verbal Order: No

Completed by Dominici, Raymond MD on 10/08/2021 12:27

Bureau of Prisons
Health Services
Clinical Encounter - Administrative Note

Inmate Name:	FATA, FARID			Reg #:	48860-039
Date of Birth:	04/09/1965	Sex:	M Race: WHITE	Facility:	WIL
Note Date:	10/08/2021 10:44	Provider:	Knox, Rodneka	Unit:	A04

POC Note - Default encounter performed at Health Services.

Administrative Notes:

ADMINISTRATIVE NOTE **1** Provider: Knox, Rodneka Phlebotomist

Urine Dipstick point of care testing completed on FATA, FARID, register number 48860-039 at 10/08/2021 10:42
Color: Red
Appearance: Clear
Glucose: Negative
Bilirubin: Negative
Ketones: Negative
Specific Gravity: 1.015
pH: 8.5
Protein: Negative
Urobilinogen: 0.2
Nitrite: Negative
Blood: 3+
Leukocyte Esterase: 1+
Reference Range: Refer to local policy
Critical Result: None

Copay Required: No **Cosign Required:** No

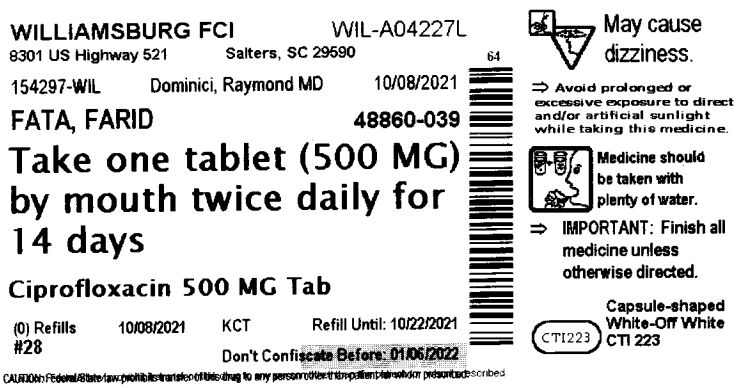
Telephone/Verbal Order: No

Completed by Knox, Rodneka Phlebotomist on 10/08/2021 10:45

Requested to be reviewed by Dominici, Raymond MD.

Review documentation will be displayed on the following page.

EXHIBIT C



WILLIAMSBURG FCI WIL-A04227L
8301 US Highway 521 Salters, SC 29590
154297-WIL Dominici, Raymond MD 10/08/2021
FATA, FARID 48860-039
Take one tablet (500 MG) by mouth twice daily for 14 days
Ciprofloxacin 500 MG Tab
(0) Refills 10/08/2021 KCT Refill Until: 10/22/2021
#28
Don't Confiscate Before: 01/06/2022
CAUTION: Federal/State law prohibits transfer of this drug to any person other than patient named on prescription or prescribed
May cause dizziness.
⇒ Avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medicine.
Medicine should be taken with plenty of water.
⇒ IMPORTANT: Finish all medicine unless otherwise directed.
CTI223
Capsule-shaped White-Off White CTI 223

WILLIAMSBURG FCI WIL-A04227L
8301 US Highway 521 Salters, SC 29590
64
154297-WIL Dominici, Raymond MD 10/08/2021
FATA, FARID 48860-039

Take one tablet (500 MG) by mouth twice daily for 14 days

Ciprofloxacin 500 MG Tab

(0) Refills 10/08/2021 KCT Refill Until: 10/22/2021
#28
Don't Confiscate Before: 01/06/2022

CAUTION: Federal/State law prohibits transfer of this drug to any person other than patient for whom prescribed.

May cause dizziness.

⇒ Avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medicine.

Medicine should be taken with plenty of water.

⇒ IMPORTANT: Finish all medicine unless otherwise directed.

CTI223 Capsule-shaped White-Off White CTI 223

EXHIBIT D

TRULINCS 48860039 - FATA, FARID - Unit: WIL-A-B

FROM:
TO: 48860039
SUBJECT: RE: SEARCH https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html
DATE: 10/13/2021 10:21:19 PM

Hospitalized or fatal COVID-19 vaccine breakthrough cases reported to CDC as of October 4, 2021
As of October 4, 2021, more than 185 million people in the United States had been fully vaccinated against COVID-19.

During the same time, CDC received reports from 50 U.S. states and territories of 30,177 patients with COVID-19 vaccine breakthrough infection who were hospitalized or died.

Total number of vaccine breakthrough infections reported to CDC

	Deaths		Hospitalized, non-fatal*	
Total	N=6,617		N=16,889	
Females	2,902	(44%)	11,474	(49%)
People aged 65 years	5,660	(86%)	15,792	(67%)
Asymptomatic or not COVID-related**	968	(15%)	3,483	(15%)

*This table separates all reported vaccine breakthrough infections that resulted in hospitalization and/or death into two columns. While most deaths were also among hospitalized individuals, a small number were not.

**Includes cases in which the patient did not have symptoms of COVID-19, or their hospitalization or death was not COVID-related. For example, people may be hospitalized for reasons other than COVID-19, such as an auto accident, and test positive when screened upon hospital admission.

Previous data on all vaccine breakthrough cases reported to CDC from January April 2021 are available.

How to interpret these data
The number of COVID-19 vaccine breakthrough infections reported to CDC are an undercount of all SARS-CoV-2 infections among fully vaccinated persons, especially of asymptomatic or mild infections. National surveillance relies on passive How to interpret these data
The number of COVID-19 vaccine breakthrough infections reported to CDC are an undercount of all SARS-CoV-2 infections among fully vaccinated persons, especially of asymptomatic or mild infections. National surveillance relies on passive and voluntary reporting, and data are not complete or representative. These surveillance data are a snapshot and help identify patterns and look for signals among vaccine breakthrough cases.

Information on patients with vaccine breakthrough infection who were hospitalized or died will continue to be updated. Studies are being conducted in multiple U.S. sites that will include information on all vaccine breakthrough infections regardless of clinical status to supplement the national surveillance.

COVID-19 vaccines are effective
To date, no unexpected patterns have been identified in the case demographics or vaccine characteristics among people with reported vaccine breakthrough infections..
COVID-19 vaccines are effective. CDC recommends that everyone 12 years of age and older get a COVID-19 vaccine as soon as they can.
A vaccine breakthrough infection happens when a fully vaccinated person gets infected with COVID-19. People with vaccine breakthrough infections may spread COVID-19 to others.
Even if you are fully vaccinated, if you live in an area with substantial or high transmission of COVID-19, you will be better protected if you wear a mask when you are in indoor public places.
Currently, CDC is recommending that moderately to severely immunocompromised people receive an additional dose of mRNA COVID-19 vaccine at least 28 days after a second dose of Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine.
For local health departments, healthcare providers, and clinical laboratories
For state health departments
How to send CDC sequence data or respiratory specimens from suspected vaccine breakthrough cases:

EXHIBIT E

Package Insert copied from:

- Drug Information Handbook
- 8th Edition
- By American Pharmacists Association
- ISBN: 978-1-59195-277-0

◆ **Cipro®** *see* Ciprofloxacin *on page 228*

◆ **Cipro® XL (Can)** *see* Ciprofloxacin *on page 228*

Ciprofloxacin (sip roe FLOKS a sin)

Medication Safety Issues

Sound-alike/look-alike issues:

Cetraxal® may be confused with cefTRIAXone

Ciprofloxacin may be confused with cephalexin

Ciloxan® may be confused with cinoxacin, Cytoxan®

Cipro® may be confused with Ceftin®

U.S. Brand Names Cetraxal®; Ciloxan®; Cipro®; Cipro® I.V.; Cipro® XR; Proquin® XR

Index Terms Ciprofloxacin Hydrochloride

Generic Available Yes: Excludes ointment, otic solution, suspension

Canadian Brand Names Apo-Ciprofloxacin®; Ciloxan®; Cipro®; Cipro® XL; CO Ciprofloxacin; Dom-Ciprofloxacin; Mint-Ciprofloxacin; Mylan-Ciprofloxacin; Novo-Ciprofloxacin; PHL-Ciprofloxacin; PMS-Ciprofloxacin; PRO-Ciprofloxacin; RAN-Ciprofloxacin; ratio-Ciprofloxacin; Riva-Ciprofloxacin; Sandoz-Ciprofloxacin; Taro-Ciprofloxacin

Pharmacologic Category Antibiotic, Ophthalmic; Antibiotic, Otic; Antibiotic, Quinolone

Use

Children: Complicated urinary tract infections and pyelonephritis due to *E. coli*

Note: Although effective, ciprofloxacin is not the drug of first choice in children.

Children and Adults: To reduce incidence or progression of disease following exposure to aerolized *Bacillus anthracis*. Ophthalmologically, for superficial ocular infections (corneal ulcers, conjunctivitis) due to susceptible strains; Auricularly, for acute otitis externa due to susceptible strains of *Pseudomonas aeruginosa* or *Staphylococcus aureus*

Adults: Treatment of the following infections when caused by susceptible bacteria: Urinary tract infections; acute uncomplicated cystitis in females; chronic bacterial prostatitis; lower respiratory tract infections (including acute exacerbations of chronic bronchitis); acute sinusitis; skin and skin structure infections; bone and joint infections; complicated intra-abdominal infections (in combination with metronidazole); infectious diarrhea; typhoid fever due to *Salmonella typhi* (eradication of chronic typhoid carrier state has not been proven); uncomplicated cervical and urethra gonorrhea (due to *N. gonorrhoeae*); nosocomial pneumonia; empirical therapy for febrile neutropenic patients (in combination with piperacillin)

Note: As of April 2007, the CDC no longer recommends the use of fluoroquinolones for the treatment of gonococcal disease.

Unlabeled/Investigational Use Acute pulmonary exacerbations in cystic fibrosis (children); cutaneous/gastrointestinal/oropharyngeal anthrax (treatment, children and adults); disseminated gonococcal infection (adults); chancroid (adults); prophylaxis to *Neisseria meningitidis* following close contact with an infected person; empirical therapy (oral) for febrile neutropenia in low-risk cancer patients; HACEK group endocarditis; infectious diarrhea (children)

Pregnancy Risk Factor C

Lactation Enters breast milk/not recommended (AAP rates "compatible")

Labeled Contraindications Hypersensitivity to ciprofloxacin, any component of the formulation, or other quinolones; concurrent administration of tizanidine

Warnings/Precautions [U.S. Boxed Warning]: There have been reports of tendon inflammation and/or rupture with quinolone antibiotics; risk may be increased with concurrent corticosteroids, organ transplant recipients, and in patients >60 years of age. Rupture of the Achilles tendon sometimes requiring surgical repair has been reported most frequently; but other tendon sites (eg, rotator cuff, biceps) have also been reported. Strenuous physical activity, rheumatoid arthritis, and renal impairment may be an independent risk factor for tendonitis. Discontinue at first sign of tendon inflammation or pain. May occur even after discontinuation of therapy. Use with caution in patients with rheumatoid arthritis; may increase risk of tendon rupture. CNS stimulation may occur (tremor, restlessness, confusion, and very rarely hallucinations or seizures). Use with caution in patients with known or suspected CNS disorder. Potential for seizures, although very rare, may be increased with concomitant NSAID therapy. Use with caution in individuals at risk of seizures. Fluoroquinolones may prolong QT_c interval; avoid use in patients with a history of QT_c prolongation, uncorrected hypokalemia, hypomagnesemia, or concurrent administration of other medications known to prolong the QT interval (including Class Ia and Class III antiarrhythmics, cisapride, erythromycin, antipsychotics, and tricyclic antidepressants). Prolonged use may result in fungal or bacterial superinfection, including *C. difficile*-associated diarrhea (CDAD) and pseudomembranous colitis; CDAD has been observed >2 months postantibiotic treatment. Rarely crystalluria has occurred; urine alkalinity may increase the risk. Ensure adequate hydration during therapy. Adverse effects, including those related to joints and/or surrounding tissues, are increased in pediatric patients and therefore, ciprofloxacin should not be considered as drug of choice in children (exception is anthrax treatment). Rare cases of peripheral neuropathy may occur.

Fluoroquinolones have been associated with the development of serious, and sometimes fatal, hypoglycemia, most often in elderly diabetics but also in patients without diabetes. This occurred most frequently with gatifloxacin (no longer available systemically), but may occur at a lower frequency with other quinolones.

Severe hypersensitivity reactions, including anaphylaxis, have occurred with quinolone therapy. Reactions may present as typical allergic symptoms after a single dose, or may manifest as severe idiosyncratic dermatologic, vascular, pulmonary, renal, hepatic, and/or hematologic events, usually after multiple doses. Prompt discontinuation of drug should occur if skin rash or other symptoms arise. Quinolones may exacerbate myasthenia gravis, use with caution (rare, potentially life-threatening weakness of respiratory muscles may occur). Use caution in renal impairment. Avoid excessive sunlight and take precautions to limit exposure (eg, loose fitting clothing, sunscreen); may cause moderate-to-severe phototoxicity reactions. Discontinue use if photosensitivity occurs. Since ciprofloxacin is ineffective in the treatment of syphilis and may mask symptoms, all patients should be tested for syphilis at the time of gonorrheal diagnosis and 3 months later. Hemolytic reactions may (rarely) occur with quinolone use in patients with latent or actual G6PD deficiency.

Ciprofloxacin is a potent inhibitor of CYP1A2. Coadministration of drugs which depend on this pathway may lead to substantial increases in serum concentrations and adverse effects.

Adverse Reactions

Systemic:

1% to 10%:

Central nervous system: Neurologic events (children 2%, includes dizziness, insomnia, nervousness, somnolence); fever (children 2%); headache (I.V. administration); restlessness (I.V. administration)

Dermatologic: Rash (children 2%, adults 1%)

Gastrointestinal: Nausea (children/adults 3%); diarrhea (children 5%, adults 2%); vomiting (children 5%, adults 1%); abdominal pain (children 3%, adults <1%); dyspepsia (children 3%)

Hepatic: ALT increased, AST increased (adults 1%)

Local: Injection site reactions (I.V. administration)

Respiratory: Rhinitis (children 3%)

<1%: Abnormal gait, acute renal failure, agitation, allergic reactions, anaphylaxis, anemia, angina pectoris, angioedema, anorexia, arthralgia, ataxia; atrial flutter, breast pain, bronchospasm, candidiasis, cardiopulmonary arrest, cerebral thrombosis, chills, cholestatic jaundice, confusion, chromatopsia, crystalluria (particularly in alkaline urine), cylindruria, depersonalization, depression, dizziness, drowsiness, dyspnea, edema, eosinophilia, erythema nodosum, fever (adults), gastrointestinal bleeding, hallucinations, headache (oral), hematuria, hyperpigmentation, hyper-/hypotension, insomnia, interstitial nephritis, intestinal perforation, irritability, joint pain, laryngeal edema, lightheadedness, lymphadenopathy, malaise, manic reaction, migraine, MI, nephritis, nightmares, palpitation, paranoia, paresthesia, peripheral neuropathy, petechia, photosensitivity, pulmonary edema, seizure, syncope, tachycardia, thrombophlebitis, tinnitus, tremor, urethral bleeding, vaginitis, ventricular ectopy, visual disturbance, weakness

Postmarketing and/or case reports: Agranulocytosis, albuminuria, anaphylactic shock, anosmia, bone marrow depression (life-threatening), candiduria, constipation, delirium, dyspepsia (adults), dysphagia, erythema multiforme, exfoliative dermatitis, fixed eruption, flatulence, hemolytic anemia, hepatic failure (some fatal), hepatic necrosis, hyperesthesia, hyperglycemia, hypertonia, jaundice, methemoglobinemia, moniliasis, myalgia, myasthenia gravis, myoclonus, nystagmus, orthostatic hypotension, pancreatitis, pancytopenia (life-threatening or fatal), pneumonitis, prolongation of PT/INR, pseudomembranous colitis, psychosis, renal calculi, serum cholesterol increased, serum glucose increased, serum sickness-like reactions, serum triglycerides increased, Stevens-Johnson syndrome, taste loss, tendon rupture, tendonitis, toxic epidermal necrolysis (Lyell's syndrome), torsade de pointes, twitching, vaginal candidiasis, vasculitis

Otic:

1% to 10%:

Central nervous system: Headache (2% to 3%)

Local: Application site pain (2% to 3%), fungal superinfection (2% to 3%), pruritus (2% to 3%)

Drug Interactions

Metabolism/Transport Effects **Inhibits** CYP1A2 (strong), 3A4 (weak)

Avoid Concomitant Use

Avoid concomitant use of Ciprofloxacin with any of the following: TiZANidine

Increased Effect/Toxicity

Ciprofloxacin may increase the levels/effects of: Bendamustine; Caffeine; Corticosteroids (Systemic); CYP1A2 Substrates; Erlotinib; Methotrexate; Pentoxifylline; QTc-Prolonging Agents; Ropinirole; Ropivacaine; Sulfonylureas; Theophylline Derivatives; TiZANidine; Vitamin K Antagonists

The levels/effects of Ciprofloxacin may be increased by: Insulin; Nonsteroidal Anti-Inflammatory Agents; P-Glycoprotein Inhibitors; Probenecid

Decreased Effect

Ciprofloxacin may decrease the levels/effects of: Mycophenolate; Phenytoin; Sulfonylureas; Typhoid Vaccine

The levels/effects of Ciprofloxacin may be decreased by: Antacids; Calcium Salts; Didanosine; Iron Salts; Magnesium Salts; P-Glycoprotein Inducers; Quinapril; Sevelamer; Sucralfate; Zinc Salts

Ethanol/Nutrition/Herb Interactions

Food: Food decreases rate, but not extent, of absorption. Ciprofloxacin serum levels may be decreased if taken with dairy products or calcium-fortified juices. Ciprofloxacin may increase serum caffeine levels if taken with caffeine.

Enteral feedings may decrease plasma concentrations of ciprofloxacin probably by >30% inhibition of absorption. Ciprofloxacin should not be administered with enteral feedings. The feeding would need to be discontinued for 1-2 hours prior to and after ciprofloxacin administration. Nasogastric administration produces a greater loss of ciprofloxacin bioavailability than does nasoduodenal administration.

Herb/Nutraceutical: Avoid dong quai, St John's wort (may also cause photosensitization).

Storage/Stability

Injection:

Premixed infusion: Store between 5°C to 25°C (41°F to 77°F); avoid freezing. Protect from light.

Vial: Store between 5°C to 30°C (41°F to 86°F); avoid freezing. Protect from light. Diluted solutions of 0.5-2 mg/mL are stable for up to 14 days refrigerated or at room temperature.

Ophthalmic solution/ointment: Store at 2°C to 25°C (36°F to 77°F). Protect from light.

Otic solution: Store at 15°C to 25°C (59°F to 77°F). Protect from light. Store unused single-dose containers in foil overwrap pouch until immediately prior to use.

Microcapsules for oral suspension: Prior to reconstitution, store below 25°C (77°F). Protect from freezing. Following reconstitution, store below 30°C (86°F) for up to 14 days. Protect from freezing.

Tablet:

Immediate release: Store below 30°C (86°F).

Extended release: Store at room temperature of 15°C to 30°C (59°F to 86°F).

Reconstitution Injection, vial: May be diluted with NS, D_5W, SWFI, $D_{10}W$, $D_5 1/4NS$, $D_5 1/2NS$, LR.

Compatibility Stable in $D_5 1/4NS$, $D_5 1/2NS$, D_5W, $D_{10}W$, LR, NS; **variable stability (consult detailed reference)** in peritoneal dialysis solution.

Y-site administration: Compatible: Amifostine, amino acids (dextrose), aztreonam, calcium gluconate, ceftazidime, cisatracurium, clarithromycin, digoxin, diltiazem, diphenhydramine, dobutamine, docetaxel, dopamine, doxorubicin liposome, etoposide phosphate, gemcitabine, gentamicin, granisetron, hydroxyzine, lidocaine, linezolid, lorazepam, metoclopramide, midazolam, midodrine, piperacillin, potassium acetate, potassium chloride, potassium phosphates, promethazine, ranitidine, remifentanil, Ringer's injection (lactated), sodium chloride, tacrolimus, teniposide, thiotepa, tobramycin, verapamil. **Incompatible:** Aminophylline, ampicillin/sulbactam, cefepime, dexamethasone sodium phosphate, furosemide, heparin, hydrocortisone sodium succinate, methylprednisolone sodium succinate,

phenytoin, propofol, sodium phosphates, warfarin. **Variable (consult detailed reference):** Magnesium sulfate, sodium bicarbonate, teicoplanin, TPN.

Compatibility when admixed: Compatible: Amikacin, aztreonam, ceftazidime, cyclosporine, gentamicin, metronidazole, netilmicin, piperacillin, potassium chloride, ranitidine, tobramycin, vitamin B complex. **Incompatible:** Aminophylline, clindamycin, floxacillin, heparin.

Mechanism of Action Inhibits DNA-gyrase in susceptible organisms; inhibits relaxation of supercoiled DNA and promotes breakage of double-stranded DNA

Pharmacodynamics/Kinetics

Absorption: Oral: Immediate release tablet: Rapid (~50% to 85%)

Distribution: V_d: 2.1-2.7 L/kg; tissue concentrations often exceed serum concentrations especially in kidneys, gallbladder, liver, lungs, gynecological tissue, and prostatic tissue; CSF concentrations: 10% of serum concentrations (noninflamed meninges), 14% to 37% (inflamed meninges)

Protein binding: 20% to 40%

Metabolism: Partially hepatic; forms 4 metabolites (limited activity)

Half-life elimination: Children: 2.5 hours; Adults: Normal renal function: 3-5 hours

Time to peak: Oral:

Immediate release tablet: 0.5-2 hours

Extended release tablet: Cipro® XR: 1-2.5 hours, Proquin® XR: 3.5-8.7 hours

Excretion: Urine (30% to 50% as unchanged drug); feces (15% to 43%)

Dosage Note: Extended release tablets and immediate release formulations are not interchangeable. Unless otherwise specified, oral dosing reflects the use of immediate release formulations.

Usual dosage ranges:

Children (see Warnings/Precautions):

Oral: 20-30 mg/kg/day in 2 divided doses; maximum dose: 1.5 g/day

I.V.: 20-30 mg/kg/day divided every 12 hours; maximum dose: 800 mg/day

Adults:

Oral: 250-750 mg every 12 hours

I.V.: 200-400 mg every 12 hours

Indication-specific dosing:

Children:

Acute otitis externa: Children ≥1 year: Refer to adult dosing

Anthrax:

Inhalational (postexposure prophylaxis):

Oral: 15 mg/kg/dose every 12 hours for 60 days; maximum: 500 mg/dose

I.V.: 10 mg/kg/dose every 12 hours for 60 days; do **not** exceed 400 mg/dose (800 mg/day)

Cutaneous (treatment, CDC guidelines): Oral: 10-15 mg/kg every 12 hours for 60 days (maximum: 1 g/day); amoxicillin 80 mg/kg/day divided every 8 hours is an option for completion of treatment after clinical improvement. **Note:** In the presence of systemic involvement, extensive edema, lesions on head/neck, refer to I.V. dosing for treatment of inhalational/gastrointestinal/oropharyngeal anthrax.

Inhalational/gastrointestinal/oropharyngeal (treatment, CDC guidelines): I.V.: Initial: 10-15 mg/kg every 12 hours for 60 days (maximum: 500 mg/dose); switch to oral therapy when clinically appropriate; refer to adult dosing for notes on combined therapy and duration

Bacterial conjunctivitis: See adult dosing

Corneal ulcer: See adult dosing

Cystic fibrosis (unlabeled use):

Oral: 40 mg/kg/day divided every 12 hours administered following 1 week of I.V. therapy has been reported in a clinical trial; total duration of therapy: 10-21 days

I.V.: 30 mg/kg/day divided every 8 hours for 1 week, followed by oral therapy, has been reported in a clinical trial

Urinary tract infection (complicated) or pyelonephritis:

Oral: 20-30 mg/kg/day in 2 divided doses (every 12 hours) for 10-21 days; maximum: 1.5 g/day

I.V.: 6-10 mg/kg every 8 hours for 10-21 days (maximum: 400 mg/dose)

Adults:

Acute otitis externa: Otic solution: Instill 0.25 mL (contents of 1 single-dose container) into affected ear twice daily for 7 days

Anthrax:

Inhalational (postexposure prophylaxis):

Oral: 500 mg every 12 hours for 60 days

I.V.: 400 mg every 12 hours for 60 days

Cutaneous (treatment, CDC guidelines): Oral: Immediate release formulation: 500 mg every 12 hours for 60 days. **Note:** In the presence of systemic involvement, extensive edema, lesions on head/neck, refer to I.V. dosing for treatment of inhalational/gastrointestinal/oropharyngeal anthrax

Inhalational/gastrointestinal/oropharyngeal (treatment, CDC guidelines): I.V.: 400 mg every 12 hours. **Note:** Initial treatment should include two or more agents predicted to be effective (per CDC recommendations). Continue combined therapy for 60 days.

Bacterial conjunctivitis:

Ophthalmic solution: Instill 1-2 drops in eye(s) every 2 hours while awake for 2 days and 1-2 drops every 4 hours while awake for the next 5 days

Ophthalmic ointment: Apply a 1/2" ribbon into the conjunctival sac 3 times/day for the first 2 days, followed by a 1/2" ribbon applied twice daily for the next 5 days

Bone/joint infections:

Oral: 500-750 mg twice daily for 4-6 weeks

I.V.: Mild-to-moderate: 400 mg every 12 hours for 4-6 weeks; Severe/complicated: 400 mg every 8 hours for 4-6 weeks

Chancroid (CDC guidelines): Oral: 500 mg twice daily for 3 days

Corneal ulcer: Ophthalmic solution: Instill 2 drops into affected eye every 15 minutes for the first 6 hours, then 2 drops into the affected eye every 30 minutes for the remainder of the first day. On day 2, instill 2 drops into the affected eye hourly. On days 3-14, instill 2 drops into affected eye every 4 hours. Treatment may continue after day 14 if re-epithelialization has not occurred.

Endocarditis due to HACEK organisms (AHA guidelines, unlabeled use): Note: Not first-line option; use only if intolerant of beta-lactam therapy:

Oral: 500 mg every 12 hours for 4 weeks

I.V.: 400 mg every 12 hours for 4 weeks

Febrile neutropenia*: I.V.: 400 mg every 8 hours for 7-14 days

Gonococcal infections:

Urethral/cervical gonococcal infections: Oral: 250-500 mg as a single dose (CDC recommends concomitant doxycycline or azithromycin due to possible coinfection with *Chlamydia*; **Note:** As of April 2007, the CDC no

longer recommends the use of fluoroquinolones for the treatment of uncomplicated gonococcal disease.

Disseminated gonococcal infection (CDC guidelines): Oral: 500 mg twice daily to complete 7 days of therapy (initial treatment with ceftriaxone 1 g I.M./I.V. daily for 24-48 hours after improvement begins); **Note:** As of April 2007, the CDC no longer recommends the use of fluoroquinolones for the treatment of more serious gonococcal disease, unless no other options exist and susceptibility can be confirmed via culture.

Infectious diarrhea: Oral:

Salmonella: 500 mg twice daily for 5-7 days

Shigella: 500 mg twice daily for 3 days

Traveler's diarrhea: Mild: 750 mg for one dose; Severe: 500 mg twice daily for 3 days

Vibrio cholerae: 1 g for one dose

Intra-abdominal*:

Oral: 500 mg every 12 hours for 7-14 days

I.V.: 400 mg every 12 hours for 7-14 days

Lower respiratory tract, skin/skin structure infections:

Oral: 500-750 mg twice daily for 7-14 days

I.V.: Mild-to-moderate: 400 mg every 12 hours for 7-14 days; Severe/complicated: 400 mg every 8 hours for 7-14 days

Nosocomial pneumonia: I.V.: 400 mg every 8 hours for 10-14 days

Prostatitis (chronic, bacterial): Oral: 500 mg every 12 hours for 28 days

Sinusitis (acute): Oral: 500 mg every 12 hours for 10 days

Typhoid fever: Oral: 500 mg every 12 hours for 10 days

Urinary tract infection:

Acute uncomplicated, cystitis:

Oral:

Immediate release formulation: 250 mg every 12 hours for 3 days

Extended release formulation (Cipro® XR, Proquin® XR): 500 mg every 24 hours for 3 days

I.V.: 200 mg every 12 hours for 7-14 days

Complicated (including pyelonephritis):

Oral:

Immediate release formulation: 500 mg every 12 hours for 7-14 days

Extended release formulation (Cipro® XR): 1000 mg every 24 hours for 7-14 days

I.V.: 400 mg every 12 hours for 7-14 days

*Combination therapy generally recommended.

Elderly: No adjustment needed in patients with normal renal function

Dosing adjustment in renal impairment: Adults:

Cl_{cr} 30-50 mL/minute: Oral: 250-500 mg every 12 hours

Cl_{cr} <30 mL/minute: Acute uncomplicated pyelonephritis or complicated UTI: Oral: Extended release formulation: 500 mg every 24 hours

Cl_{cr} 5-29 mL/minute:

Oral: 250-500 mg every 18 hours

I.V.: 200-400 mg every 18-24 hours

Dialysis: Only small amounts of ciprofloxacin are removed by hemo- or peritoneal dialysis (<10%); usual dose: Oral: 250-500 mg every 24 hours following dialysis

Continuous renal replacement therapy (CRRT): I.V.:

CVVH: 200 mg every 12 hours

CVVHD or CVVHDF: 200-400 mg every 12 hours

Administration

Ophthalmic ointment/solution: For topical ophthalmic use only; avoid touching tip of applicator to eye or other surfaces.

Oral: May administer with food to minimize GI upset; avoid antacid use; maintain proper hydration and urine output. Administer immediate release ciprofloxacin and Cipro® XR at least 2 hours before or 6 hours after, and Proquin® XR at least 4 hours before or 6 hours after antacids or other products containing calcium, iron, or zinc (including dairy products or calcium-fortified juices). Separate oral administration from drugs which may impair absorption (see Drug Interactions).

Oral suspension: Should not be administered through feeding tubes (suspension is oil-based and adheres to the feeding tube). Patients should avoid chewing on the microcapsules.

Nasogastric/orogastric tube: Crush immediate-release tablet and mix with water. Flush feeding tube before and after administration. Hold tube feedings at least 1 hour before and 2 hours after administration.

Tablet, extended release: Do not crush, split, or chew. May be administered with meals containing dairy products (calcium content <800 mg), but not with dairy products alone. Proquin® XR should be administered with a main meal of the day; evening meal is preferred.

Otic solution: For otic use only. Prior to use, warm solution by holding container in hands for at least 1 minute. Patient should lie down with affected ear upward and medication instilled. Patients should remain in the position for at least 1 minute to allow penetration of solution.

Parenteral: Administer by slow I.V. infusion over 60 minutes to reduce the risk of venous irritation (burning, pain, erythema, and swelling); final concentration for administration should not exceed 2 mg/mL.

Monitoring Parameters CBC, renal and hepatic function during prolonged therapy

Test Interactions Some quinolones may produce a false-positive urine screening result for opiates using commercially-available immunoassay kits. This has been demonstrated most consistently for levofloxacin and ofloxacin, but other quinolones have shown cross-reactivity in certain assay kits. Confirmation of positive opiate screens by more specific methods should be considered.

Dietary Considerations

Food: Drug may cause GI upset; take without regard to meals (manufacturer prefers that immediate release tablet is taken 2 hours after meals). Extended release tablet may be taken with meals that contain dairy products (calcium content <800 mg), but not with dairy products alone.

Dairy products, calcium-fortified juices, oral multivitamins, and mineral supplements: Absorption of ciprofloxacin is decreased by divalent and trivalent cations. The manufacturer states that the usual dietary intake of calcium (including meals which include dairy products) has not been shown to interfere with ciprofloxacin absorption. Immediate release ciprofloxacin and Cipro® XR may be taken 2 hours before or 6 hours after, and Proquin® XR may be taken 4 hours before or 6 hours after, any of these products.

Caffeine: Patients consuming regular large quantities of caffeinated beverages may need to restrict caffeine intake if excessive cardiac or CNS stimulation occurs.

Additional Information Although the systemic use of ciprofloxacin is only FDA approved in children for the treatment of complicated UTI and postexposure treatment of inhalation anthrax, use of the fluoroquinolones in pediatric patients is increasing. Current recommendations by the American

EXHIBIT F

TRULINCS 48860039 - FATA, FARID - Unit: WIL-A-B

FROM: 48860039
TO: Goldberg, Jack
SUBJECT: SECOND OPINION
DATE: 10/11/2021 09:05:20 AM

Dear Dr. Goldberg,

I am still waiting on my Judge to rule on my compassionate release upon the COVID virus, as I am immuno-compromised and suffer recurrent infections with high risk to develop breakthrough COVID as FCI Williamsburg is still operating at the highest Level 3 COVID-19 Pandemic Plan. Recently (beginning September 2021), we were on lockdown for one week as two inmates tested positive, became sick and were isolated.

Over the past 4 weeks, I have been experiencing urinary burning, frequent urination, noctiuria, and pelvic pain.

On October 8, 2021, the Bureau provider diagnosed me with acute on chronic prostatitis, proven on urinalysis with the presence of blood, nitrite positive, leucocytes positive. He prescribed ciprofloxacin for 14 days as the BOP formulary only allows a 2 week treatment (endorsed by the pharmacist here at FCI Williamsburg). Though the Bureau provider acknowledged that the standard FDA label recommends 4 week antibiotic treatment for prostatitis, he said he has to follow the BOP formulary even knowing that it defies the FDA label.

Dr. Goldberg: I am concerned and perplexed. I need your expert opinion. Does this short cut treatment put me at risk for recurrent prostatitis and Urinary Tract infection due to my underlying diabetes and neutropenia ? Any ideas or guidance I can learn from you ?

I will submit your response to the Court as my medical care cannot be met in BOP custody

Please advise

TRULINCS 48860039 - FATA, FARID - Unit: WIL-A-B

FROM: Goldberg, Jack
TO: 48860039
SUBJECT: RE: SECOND OPINION
DATE: 10/12/2021 11:51:17 PM

Chronic Bacterial Prostatitis ← ciprofloxacin

Treatment success rates with the administration of trimethoprim-sulfamethoxazole (TMP-SMZ) approach 30%-40%, while success rates with fluoroquinolones are 40%-75%. Relapses are common and can be treated with another course of antibiotics. If repeat treatment fails, consider a low, suppressive dose of antibiotics.

Infection often persists because antibiotics do not penetrate the prostate easily and no active transport mechanism exists whereby antibiotics can enter the prostatic ducts. Another inhibiting factor is that prostatic fluid is acidic compared with plasma, thus creating a pH gradient that further inhibits diffusion of acidic antibiotics into the prostatic fluid.

Morbidity and mortality

Prostatitis can impair the patient's quality of life to the same degree as coronary artery disease or Crohn disease. Studies show that prostatitis has the same effect on a patient's mental health as do diabetes mellitus and chronic heart failure. [21]

A retrospective study suggested that a relationship exists between the severity of chronic prostatitis symptoms and erectile dysfunction frequency. Whether this relationship is mediated through organic or psychological mechanisms has remained unclear. [22] In a comparison of data from 317 patients with chronic bacterial prostatitis (CBP) due to C trachomatis and 639 patients with CBP caused by common uropathogenic bacteria, Cai and colleagues reported that patients with chlamydial CBP reported a higher prevalence of premature ejaculation and lower quality of life. [23]

Alkan et al reported that levels of superoxide anion and total reactive oxygen species (ROS) were significantly higher in the semen of men with category IIIA chronic prostatitis/chronic pelvic pain syndrome compared with healthy controls, and that those levels correlated negatively with scores on an erectile dysfunction questionnaire. These authors suggest that overproduction of superoxide anion and ROS could be one of the important mechanisms for erectile dysfunction in these patients. [24]

In a study of 110 infertile men with CBP, the 78 patients who responded to levofloxacin treatment (as indicated by eradication of bacteria from sperm cultures) showed showed a significant increase in sperm progressive motility and a significant decrease in seminal leukocyte count, seminal fluid viscosity, liquefaction time, reactive oxygen species production, and seminal tumor necrosis factor-a and interleukin-6 levels. None of those posttreatment variables were significantly different than those in a control group of 37 fertile men. In the patients with poor antibiotic responsiveness, however, all measured semen variables showed deterioration. [25]

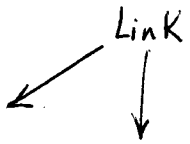
There is concern that clinical chronic prostatitis may be a risk factor for prostate cancer. Two separate meta-analyses and other large case-control studies have estimated a 60% increased risk of prostate cancer in patients with symptomatic prostatitis in white men. [26] However, African Americans have been shown in one study to actually have a slightly decreased risk of prostate cancer with symptomatic prostatitis. [26]

Some studies report that men with prostate cancer have histological prostatic inflammation 4-5 times more often than men without prostate cancer. Other studies have suggested that histological prostatic inflammation in benign prostate tissue specimens from asymptomatic men are associated with decreased future prostate cancer risk. [26] As mentioned previously, prostatic inflammation is a nonspecific finding, and its relation to prostate cancer is also unclear.

CBP is not associated with mortality. However, acute bacterial prostatitis represents a potentially lethal process if untreated.

TRULINCS 48860039 - FATA, FARID - Unit: WIL-A-B

FROM: Goldberg, Jack
TO: 48860039
SUBJECT: RE: https link
DATE: 10/13/2021 11:51:17 PM



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Users/jackgoldberg/Library/Containers/com.apple.mail/Data/Library/Mail Downloads/4B82F4C5-049E-4BAF-B7CC-AC42EA30A22B/WebPage.pdf

FARID FATA on 10/13/2021 8:21:37 AM wrote
Dear Dr. Goldberg,

can you email me the website link related to the medical info you sent me.

Thank you so much

TRULINCS 48860039 - FATA, FARID - Unit: WIL-A-B

FROM:
TO: 48860039
SUBJECT: https://www.medicalnewstoday.com/articles/322457
DATE: 10/13/2021 10:36:11 PM

https://www.medicalnewstoday.com/articles/n

Causes and treatment of chronic prostatitis

What is chronic prostatitis?
Causes
Symptoms
Diagnosis
Treatment
Outlook
Chronic prostatitis is inflammation of the prostate that continues for 3 months or longer. It is often painful and can affect sexual function and the ability to urinate. Many health issues, including recurrent bacterial infections and damage to the nerves or muscles in the pelvic area, can cause it.

In this article, we look at the causes and symptoms of chronic prostatitis. We also cover diagnosis, treatment, and home and alternative remedies.

What is chronic prostatitis?
Man discussing Chronic prostatitis with male doctor in office.
Share on Pinterest

The prostate is a small gland that forms part of the lower urinary tract in males. It sits under the bladder and surrounds the urethra, which is the tube that carries urine and semen out through the penis.

The prostate is part of the male reproductive system and produces one of the fluids that make up semen. The muscles of this gland also help push semen into the urethra during ejaculation.

Due to its location and function, problems with the prostate can affect urination as well as sexual function.

Prostatitis is an inflammation of the prostate that can often be painful. It can be chronic or acute:

Chronic prostatitis develops gradually and can last for months or even years. Doctors consider prostatitis to be chronic if symptoms continue for 3 months or moreTrusted Source. It may not respond well to the first treatments a doctor recommends.
Acute prostatitis is a temporary condition that occurs suddenly. It may only last a few days or weeks and often responds well to treatment.
Prostatitis is the leading causeTrusted Source of urinary tract issues for men under 50 years of age, and the third most common urinary tract issue for men over 50 years of age.

Causes
An accurate diagnosis is key to effective treatment. However, diagnosing the cause of chronic prostatitis can sometimes prove challenging.

The causes of chronic prostatitis fall into two broad categories:

Chronic bacterial prostatitis

A bacterial infection of the prostate causes chronic bacterial prostatitis. In some people, this infection develops following a urinary tract infection or treatment for acute bacterial prostatitis.

The symptoms of chronic bacterial prostatitis are often less severe than those of acute bacterial prostatitis. A person who has previously had an acute infection might notice that their symptoms get better, but do not go away.

Some people with chronic bacterial prostatitis may find that the infection persists. This may be because the bacteria are resistant to antibiotic treatment or the antibiotic treatment course is too short. According to one studyTrusted Source, some

bacteria that infect the prostate can form biofilms in animals. Biofilms are similar to the plaque that develops on teeth and can make the infection harder to treat.

Chronic non-bacterial prostatitis, or chronic pelvic pain syndrome

This is a non-bacterial form of prostatitis that can have many causes and is harder to treat. Someone who has had a previous bacterial infection of the prostate may be at risk of developing this type of prostatitis. Other people may develop chronic

EXHIBIT G

TRULINCS 48860039 - FATA, FARID - Unit: WIL-A-B

FROM: 48860039
TO: Provider
SUBJECT: ***Request to Staff*** FATA, FARID, Reg# 48860039, WIL-A-B
DATE: 10/12/2021 08:56:01 PM

To: Dr. Dominici
Inmate Work Assignment: UNICOR

Dr. Dominici,

As you recall, you diagnosed me with prostatitis on October 8, 2021 and prescribed a 2 week-course of ciprofloxacin.

It came to my attention that the package insert and FDA label of Cipro notes that prostatitis is treated with a 28 day course of cipro instead. Medical Textbooks also state the same duration of antibiotic therapy (Harrison's Textbook of Internal Medicine recommends 4 week-course).

I need guidance. Please advise

P.S.
the Bureau Provider did not reply. Fata spoke to Pharmacy Staff: BOP has no clinical Pathways established to treat chronic Prostatitis; therefore, they have no medical data to support a short, incomplete antibiotic Course.

EXHIBIT H

TRULINCS 48860039 - FATA, FARID - Unit: WIL-A-B

FROM: 48860039
TO: Provider
SUBJECT: ***Request to Staff*** FATA, FARID, Reg# 48860039, WIL-A-B
DATE: 10/16/2021 07:40:59 AM

To: Dr. Dominici
Inmate Work Assignment: UNICOR

Dear Dr. Dominici,

I have sent you an email on 10-12-2021, but have not heard from you. My off-site doctor Dr. Jack Goldberg, MD, FACP has opined that the standard treatment of Chronic prostatitis is 28 days of antibiotic. He has sent me references and links that support the concept that "a short treatment course can lead to recurrent prostatitis, and possible long term complications of chronic pelvic pain syndrome, erectile dysfunction, and even prostate cancer.

https://www.aafp.org/afp/2016/0115/afp20160115p114.pdf

https://www.medicalnewstoday.com/articles/322457

I am concerned and ask you to reconsider the short course of ciprofloxacin

Please advise

P.S.
On 10-18-2021, Fata requested to meet the Provider again to discuss his concerns. Fata is on day 7 of ciprofloxacin. His urological symptoms of urinary burning (scrotal), frequent repetitive Urination at night, and pelvic pain are persistent.
During Mainline, Fata addressed his concerns with Associate Warden Mr. Mendoza.
Later, Fata was notified to Watch [redacted] for Callout to see the Provider again.

EXHIBIT I

Individualized Needs Plan - Program Review (Inmate Copy)

SEQUENCE: 01848271

Dept. of Justice / Federal Bureau of Prisons

Team Date: 09-14-2021

Plan is for inmate: FATA, FARID 48860-039

Facility:	WIL WILLIAMSBURG FCI	Proj. Rel. Date:	12-11-2051
Name:	FATA, FARID	Proj. Rel. Mthd:	GCT REL
Register No.:	48860-039	DNA Status:	MIL05699 / 08-28-2013
Age:	56		
Date of Birth:	04-09-1965		

Detainers

Detaining Agency	Remarks

NO DETAINER

Current Work Assignments

Facl	Assignment	Description	Start
WIL	UNICOR	UNICOR	02-26-2021

Current Education Information

Facl	Assignment	Description	Start
WIL	ESL HAS	ENGLISH PROFICIENT	09-03-2015
WIL	GED HAS	COMPLETED GED OR HS DIPLOMA	09-03-2015

Education Courses

SubFacl	Action	Description	Start	Stop
WIL		RPP #1 - DIABETES CLASS	07-16-2021	CURRENT
WIL	C	INTRODUCTION TO BAND	06-24-2021	07-11-2021
WIL	C	GUITAR CARE	06-24-2021	07-11-2021
WIL	C	HEALTH FAIR-VARIOUS TOPICS	05-30-2021	07-07-2021
WIL	C	SHU MEN'S HEALTH	01-01-2021	03-22-2021
WIL	C	HEALTH FAIR-VARIOUS TOPICS	11-23-2020	12-18-2020
WIL	C	SHU NUTRITION	08-21-2020	12-18-2020
WIL	C	BEGINNING FRENCH	01-21-2020	10-05-2020
WIL	C	INTERMEDIATE PIANO	01-12-2020	03-31-2020
WIL	C	STARTING AND INCORPRATE A BUS	03-05-2019	05-24-2019
WIL	C	BEGINNING FRENCH	03-05-2019	05-24-2019
WIL	C	ADVANCE FRENCH	11-16-2018	02-25-2019
WIL	C	STARTING AND INCORPRATE A BUS	11-16-2018	02-25-2019
WIL	C	ART HISTORY-VARIOUS TOPICS	12-26-2018	12-28-2018
WIL	C	BEGINNING FRENCH	08-09-2018	10-31-2018
WIL	C	HEALTH FAIR-VARIOUS TOPICS	09-25-2018	09-28-2018
WIL	C	STARTING AND INCORPRATE A BUS	05-09-2018	07-27-2018
WIL	C	ADVANCE FRENCH	05-09-2018	07-27-2018
WIL	C	BEGINING FRENCH	02-01-2018	05-11-2018
WIL	C	UNDERSTANDING BASIC LAW	02-01-2018	05-09-2018
WIL	C	INDEPENDENT OWNER TRUCKING	02-01-2018	05-09-2018
WIL	C	HEALTH FAIR-VARIOUS TOPICS	04-24-2018	05-07-2018
WIL	C	CUSTODIAL APPRENTICE	03-14-2017	05-04-2018
WIL	C	INTERMEDIATE SPANISH	10-24-2017	01-19-2018
WIL	C	ADVANCE LAW	10-24-2017	01-12-2018
WIL	C	INTERMEDIATE FRENCH	10-25-2017	01-12-2018
WIL	C	HEALTH FAIR-VARIOUS TOPICS	09-27-2017	10-03-2017
WIL	C	BEGINNING SPANISH	07-27-2017	10-10-2017
WIL	C	BEGINING FRENCH	07-27-2017	10-10-2017
WIL	C	STARTING AND INCORPRATE A BUS	04-14-2017	06-30-2017
WIL	C	BEGINNING SPANISH	04-14-2017	06-30-2017
WIL	C	ART HISTORY-VARIOUS TOPICS	05-31-2017	06-10-2017
WIL	C	HEALTH FAIR-VARIOUS TOPICS	04-25-2017	05-07-2017
WIL	C	RPP #6 DRUG EDUCATION	08-22-2016	10-21-2016
WIL	C	FCI ORIGAMI LEISURE CLASS	06-24-2016	08-16-2016
WIL	C	TEACH ENGLISH TO SPANISH	05-18-2016	08-12-2016
WIL	C	TYPING I	05-20-2016	08-12-2016

Individualized Needs Plan - Program Review (Inmate Copy)

SEQUENCE: 01848271

Dept. of Justice / Federal Bureau of Prisons

Team Date: 09-14-2021

Plan is for inmate: FATA, FARID 48860-039

SubFacl	Action	Description	Start	Stop
WIL	C	FCI CDL PREP CLASS	05-17-2016	08-05-2016
WIL	C	RPP#1-MEN'S HEALTH CLASS	03-28-2016	06-15-2016
WIL	C	RPP#1-ENDURANCE TRAINING CLASS	03-28-2016	06-15-2016
WIL	C	HEALTH FAIR-VARIOUS TOPICS	04-27-2016	05-17-2016
WIL	C	INVESTING / ACE COURSE	02-11-2016	05-16-2016
WIL	C	JOB FAIR INFORMATIONAL	03-09-2016	05-10-2016
WIL	C	COMPUTER APPLS SKILL IMPROVMEN	02-18-2016	05-10-2016
WIL	C	BEGINNER'S DRUM CLASS	09-03-2015	12-03-2015
WIL	C	REC MUSIC CLASS	01-13-2016	03-28-2016
WIL	C	TYPING I	12-04-2015	02-16-2016
WIL	C	REC MUSIC CLASS	09-03-2015	12-03-2015
WIL	C	BUSINESS MARKETING & ADMIN COM	10-02-2015	02-01-2016
WIL	C	HEALTH FAIR-VARIOUS TOPICS	10-29-2015	10-29-2015
WIL	C	RPP #1 HIV/AIDS AWARENESS	09-14-2015	09-14-2015

Discipline History (Last 6 months)

Hearing Date	Prohibited Acts

*** NO INCIDENT REPORTS FOUND IN LAST 6 MONTHS ***

Current Care Assignments

Assignment	Description	Start
CARE1	HEALTHY OR SIMPLE CHRONIC CARE	10-31-2019
CARE1-MH	CARE1-MENTAL HEALTH	07-20-2015

Current Medical Duty Status Assignments

Assignment	Description	Start
NO PAPER	NO PAPER MEDICAL RECORD	08-28-2013
REG DUTY	NO MEDICAL RESTR--REGULAR DUTY	01-19-2017
YES F/S	CLEARED FOR FOOD SERVICE	10-31-2019

Current Drug Assignments

Assignment	Description	Start
ED COMP	DRUG EDUCATION COMPLETE	10-21-2016
NR WAIT	NRES DRUG TMT WAITING	06-08-2016

FRP Payment Plan

Most Recent Payment Plan

FRP Assignment: PART FINANC RESP-PARTICIPATES Start: 03-07-2016

Inmate Decision: **AGREED** **$25.00** Frequency: **QUARTERLY**

Payments past 6 months: **$50.00** Obligation Balance: **$26,480,755.37**

Financial Obligations

No.	Type	Amount	Balance	Payable	Status
2	REST FV	$26,480,880.37	$26,480,755.37	IMMEDIATE	AGREED

Adjustments:	Date Added	Facl	Adjust Type	Reason	Amount
	09-11-2021	WIL	PAYMENT	INSIDE PMT	$25.00
	06-11-2021	WIL	PAYMENT	INSIDE PMT	$25.00

1	ASSMT	$1,600.00	$1,225.00	DEFERRED	EXPIRED

*** NO ADJUSTMENTS MADE IN LAST 6 MONTHS ***

FRP Deposits

Trust Fund Deposits - Past 6 months: $1,364.00 Payments commensurate ? N/A

New Payment Plan: ** No data **

Current FSA Assignments

Assignment	Description	Start
FTC ELIG	FTC-ELIGIBLE - REVIEWED	07-10-2020

Individualized Needs Plan - Program Review (Inmate Copy)

SEQUENCE: 01848271

Dept. of Justice / Federal Bureau of Prisons

Team Date: 09-14-2021

Plan is for inmate: FATA, FARID 48860-039

Assignment	Description	Start
N-ANGER N	NEED - ANGER/HOSTILITY NO	05-31-2021
N-ANTISO N	NEED - ANTISOCIAL PEERS NO	05-31-2021
N-COGNTV N	NEED - COGNITIONS NO	05-31-2021
N-DYSLEX N	NEED - DYSLEXIA NO	05-31-2021
N-EDUC N	NEED - EDUCATION NO	05-31-2021
N-FIN PV N	NEED - FINANCE/POVERTY NO	05-31-2021
N-FM/PAR N	NEED - FAMILY/PARENTING NO	05-31-2021
N-M HLTH N	NEED - MENTAL HEALTH NO	05-31-2021
N-MEDICL N	NEED - MEDICAL NO	05-31-2021
N-RLF Y	NEED - REC/LEISURE/FITNESS YES	05-31-2021
N-SUB AB Y	NEED - SUBSTANCE ABUSE YES	05-31-2021
N-TRAUMA N	NEED - TRAUMA NO	05-31-2021
N-WORK N	NEED - WORK NO	05-31-2021
R-MIN	MINIMUM RISK RECIDIVISM LEVEL	04-28-2021

Progress since last review

Due to COVID 19 restrictions, goals couldn't be completed from last program review.

Next Program Review Goals

Unit team suggest Mr. Fata Complete one day of ROP by next program review. Unit team suggest Mr. Fata obtain application for Birth Certificate and Social Security Card by next program review.

Long Term Goals

Unit Team suggest Mr. Fata complete all ROP Program by release date of 2034. Unit team suggest Mr. Fata obtain Birth Certificate and Social Security card by release date.

RRC/HC Placement

No.
Management decision - Will discuss 17-19 months prior to release date, if eligible..
Consideration has been given for Five Factor Review (Second Chance Act):
- Facility Resources : RRC Available
- Offense : Instant offense fraud
- Prisoner : There are no extenuating circumstances that would preclude placement.
- Court Statement : none
- Sentencing Commission : none

Will review 17-19 months from release date

Comments

** No notes entered **

Individualized Needs Plan - Program Review (Inmate Copy) SEQUENCE: 01848271
Dept. of Justice / Federal Bureau of Prisons Team Date: 09-14-2021
Plan is for inmate: FATA, FARID 48860-039

Name: FATA, FARID
Register No.: 48860-039
Age: 56
Date of Birth: 04-09-1965

DNA Status: MIL05699 / 08-28-2013

Inmate (FATA, FARID. Register No.: 48860-039)

Date

Unit Manager / Chairperson

Case Manager

Date

Date

EXHIBIT J

U.S. Department of Justice

Federal Bureau of Prisons

MEMORANDUM FOR ALL INMATES
FCI WILLIAMSBURG

August 18, 2021

FROM: A. Mendoza, Acting Warden
FCI Williamsburg

SUBJECT: COVID-19 Modified Operations

Effective Monday, August 23, 2021, the Bureau will implement new COVID-19 operational levels in consideration of recently published CDC guidance for correctional institutions. The COVID-19 operational levels are based upon a color-coded tiered approach that will permit operations to continue in a safe, secure manner while adjusting previously adopted COVID-19 mitigation strategies.

The tiered approach addresses infection control measures, inmate programing and service needs, movement, and staff screening/testing guidance in accordance with the continued use of the BOP's COVID-19 Pandemic Plan.

This tiered approach utilizes three indicators for each institution to determine a modified operations level. The modified operations level is monitored daily by the institution Health Services Administrator, (or designee,) and reported to the Warden at each respective location. The Warden retains authority for all operational decisions.

The three indicators utilized are: 1) medical isolation rate within the institution (active cases); 2) facility vaccination rates (includes staff and inmates); and 3) community transmission rates in the surrounding communities of our institutions. A percentage-based formula is applied to these three indicators and determines the level of modified operations. Those levels are: Level 1 Operations-Minimal Modifications (commonly referred to as Green), Level 2 Operations-Moderate Modifications (commonly referred to as Yellow), and Level 3 Operations-Intense Modifications (commonly referred to as Red).

U.S. Department of Justice

Federal Bureau of Prisons

Federal Correctional Institution, Williamsburg

Salters, South Carolina

September 10, 2021

MEMORANDUM FOR INMATE POPULATION

FROM: //s//
D. Waycaster, Acting Associate Warden
FCI Williamsburg

SUBJECT: Mandatory Face covering/Masking Guidance

Mandatory facility-wide face coverings are still in effect per the COVID-19 Pandemic Plan. In an effort to ensure all inmates are properly wearing an appropriate face covering the following reissuance will occur.

On Monday September 13, 2021, Unit Team will be exchanging your used face coverings for 2 new cloth face masks in addition to 2 surgical grade face masks. The surgical grade facemasks are to be utilized when reporting to the Health Services Department for your medical call outs or working with your work detail in that area. Surgical masks are required, per the COVID-19 guidelines, within all patient care areas, whether or not there are patients in the clinic area.

Also note that due to the local community COVID-19 infection rates we are following the Level 3 Operations Intense Modifications guidance for all other areas.

FATA, FARID 48860039

EXHIBIT K

TRULINCS 48860039 - FATA, FARID - Unit: WIL-A-B

FROM: Goldberg, Jack
TO: 48860039
SUBJECT: RE: Booster Dose - SECOND OPINION
DATE: 08/13/2021 10:36:28 PM

From:
www.medscape.com

CDC Officially Endorses Third Dose of mRNA Vaccines for Immunocompromised

Editor's note: Find the latest COVID-19 news and guidance in Medscape's Coronavirus Resource Center.

Centers for Disease Control and Prevention (CDC) Director Rochelle Walensky, MD, has officially signed off on a recommendation by an independent panel of 11 experts to allow people with weakened immune function to get a third dose of certain COVID-19 vaccines.

The decision follows a unanimous vote by the CDC's Advisory Committee on Immunization Practices (ACIP), which in turn came hours after the US Food and Drug Administration (FDA) updated its Emergency Use Authorization (EUA) for the Pfizer and Moderna mRNA vaccines.

About 7 million adults in the United States have moderately to severely impaired immune function because of a medical condition they live with or a medication they take to manage a health condition.

People who fall into this category are at higher risk of being hospitalized or dying if they get COVID-19. They are also more likely to transmit the infection. About 40% of vaccinated patients who are hospitalized with breakthrough cases are immunocompromised.

Recent studies have shown that between one-third and one-half of immunocompromised people who didn't develop antibodies after two doses of a vaccine do get some level of protection after a third dose.

Even then, however, the protection immunocompromised people get from vaccines is not as robust as someone who has healthy immune function, and some panel members were concerned that a third dose might come with a false sense of security.

"My only concern with adding a third dose for the immunocompromised is the impression that our immunocompromised population [will] then be safe," said ACIP member Helen Talbot, MD, MPH, an associate professor of medicine at Vanderbilt University Medical Center in Nashville, Tennessee.

"I think the reality is they'll be safer, but still at incredibly high risk for severe disease and death," she said.

In updating its EUA, the FDA stressed that, even after a third dose, people who are immunocompromised will still need to wear a mask indoors, socially distance, and avoid large crowds. In addition, family members and other close contacts should be fully vaccinated to protect these vulnerable individuals.

Johnson and Johnson Not in the Mix

The boosters will be available to children as young as 12 years of age who've had a Pfizer vaccine or those ages 18 and older who've gotten the Moderna vaccine.

For now, people who've had the one-dose Johnson and Johnson vaccine have not been cleared to get a second dose of any vaccine.

FDA experts acknowledged the gap but said that people who had received the Johnson and Johnson vaccine represented a small slice of vaccinated Americans, and said they couldn't act before the FDA had updated its authorization for that vaccine, which the agency is actively exploring.

"We had to do what we're doing based on the data we have in hand," said Peter Marks, MD, director of the Center for Biologics Evaluation and Research at the FDA, the division of the agency that regulates vaccines.

"We think at least there is a solution here for the very large majority of immunocompromised individuals and we believe we will probably have a solution for the remainder in the not-too-distant future," Marks said.

In its updated EUA, the FDA said that the third shots were intended for people who had undergone solid organ transplants or have an "equivalent level of immunocompromise."

The Details

Clinical experts on the CDC panel spent a good deal of time trying to suss out exactly what conditions might fall under the FDA's umbrella for a third dose.

In a presentation to the committee, Neela Goswami, MD, PhD, an assistant professor of infectious diseases at Emory University School of Medicine and of epidemiology at the Emory Rollins School of Public Health, in Atlanta, Georgia, stressed that the shots are intended for patients who are moderately or severely immunocompromised, in close consultation with their doctors, but that people who should qualify would include those:

In discussion, CDC experts clarified that these third doses were not intended for people whose immune function had waned with age, such as elderly residents of long-term care facilities, or people with chronic diseases like diabetes.

The idea is to try to get a third dose of the vaccine they've already had Moderna or Pfizer but if that's not feasible, it's fine for the third dose to be different from what someone has had before. The third dose should be given at least 28 days after a second dose, and, ideally, before the initiation of immunosuppressive therapy.

Participants in the meeting said that the CDC would post updated materials on its website to help guide physicians on exactly who should receive third doses.

Ultimately, however, the extra doses will be given on an honor system; no prescriptions or other kinds of clinical documentation will be required for people to get a third dose of these shots.

Tests to measure neutralizing antibodies are also not recommended before the shots are given because of differences in the types of tests used to measure these antibodies and the difficulty in interpreting them. It's unclear right now what level of neutralizing antibodies is needed for protection..

"Peace of Mind"

In public testimony, Heather Braaten, a 44-year-old being treated for ovarian cancer, said she was grateful to have gotten two shots of the Pfizer vaccine last winter, in between rounds of chemotherapy, but she knew she was probably not well protected. She said she'd become obsessive over the past few months reading medical studies trying to understand her risk.

"I have felt distraught over the situation. My prognosis is poor. I most likely have about two to three years left to live, so everything counts," Braaten said.

She said her life ambitions were humble. She wants to visit with friends and family and not have to worry that she'll be a breakthrough case. She wants to go grocery shopping again and "not panic and leave the store after five minutes." She'd love to feel free to travel, she said.

"While I understand I still need to be cautious, I am hopeful for the peace of mind and greater freedom a third shot can provide," Braaten said.

More Boosters on the Way?

In the second half of the meeting, the CDC also signaled that it was considering the use of boosters for people whose immunity might have waned in the months since they had completed their vaccine series, particularly seniors. About 75% of people hospitalized with vaccine breakthrough cases are over age 65, according to CDC data.

Those considerations are becoming more urgent as the Delta variant continues to pummel less vaccinated states and counties.

In its presentation to the ACIP, Heather Scobie, PhD, MPH, a member of the CDC's COVID Response Team, highlighted data from Canada, Israel, Qatar, and the United Kingdom showing that, while the Pfizer vaccine was still highly effective at preventing hospitalizations and death, it's far less likely when faced with Delta to prevent an infection that causes symptoms.

In Israel, Pfizer's vaccine prevented symptoms an average of 41% of the time. In Qatar, which is also using the Moderna

TRULINCS 48860039 - FATA, FARID - Unit: WIL-A-B

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vaccine, Pfizer's prevented symptomatic infections with Delta about 54% of the time compared with 85% with Moderna's.

Scobie noted that Pfizer's waning efficacy may have something to do with the fact that it uses a lower dosage than Moderna's. Pfizer's recommended dosing interval is also shorter 3 weeks compared with 4 weeks for Moderna's. Stretching the time between shots has been shown to boost vaccine effectiveness, she said.

New data from the Mayo clinic, published ahead of peer review, also suggest that Pfizer's protection may be fading more quickly than Moderna's.

In February, both shots were nearly 100% effective at preventing the SARS-CoV-2 infection, but by July, against Delta, Pfizer's efficacy had dropped to somewhere between 13% and 62%, while Moderna's was still effective at preventing infection between 58% and 87% of the time.

In July, Pfizer's was between 24% and 94% effective at preventing hospitalization with a COVID-19 infection and Moderna's was between 33% and 96% effective at preventing hospitalization.

While that may sound like cause for concern, Scobie noted that, as of August 2, severe COVD-19 outcomes after vaccination are still very rare. Among 164 million fully vaccinated people in the United States there have been about 7000 hospitalizations and 1500 deaths; nearly three out of four of these have been in people over the age of 65.

The ACIP will next meet on August 24 to focus solely on the COVID-19 vaccines.

FARID FATA on 8/13/2021 7:21:42 PM wrote
Dear Dr. Goldberg,

I need your expert opinion with respect to the need for a COVID vaccine third booster dose per FDA recommendation that the CDC signed off today August 13, 2021: As you know, I am immunocompromised with neutropenia and suffered recurrent infections (COVID-19, recurrent skin infections, periapical abscess as shown on colonoscopy ... etc).

The Bureau provider here at FCI Williamsburg is waiting on receiving guidance from the BOP which may take weeks, if not, months. At this time, FCI Williamsburg Health Services will not proceed on the booster shots .

Meanwhile, I have spoken to one Bureau doctor to at least obtain antibody testing to check whether I have generated an antibody response to the Pfizer vaccine and requested it in writing. Unfortunately, I was told that BOP does not do this type of specific antibody testing.

EXHIBIT L

TRULINCS 48860039 - FATA, FARID - Unit: WIL-A-B

FROM: Provider
TO: 48860039
SUBJECT: RE:***Inmate to Staff Message***
DATE: 08/15/2021 02:42:04 PM

No
However all BOP guidelines will be followed. It is recommended that you wear your mask

>>> ~^!"FATA, ~^!FARID" <48860039@inmatemessage.com> 8/13/2021 6:44 PM >>>
To: Mr. Davis
Inmate Work Assignment: UNICOR

Until you receive guidance from the BOP, meanwhile, Can you please order antibody testing as recommended by the CDC

in immunocompromised patients. The NIH and Johns Hopkins have both published that absent antibody response to the

COVID vaccine is a strong indicator for a need of a booster dose in immunocompromised patients

Please advise
-----Provider on 8/13/2021 8:02 AM wrote:

>
Once guidance comes down from the Bureau of Prisons, the health services department will make every effort to comply with all COVID related guidelines

>>> ~^!"FATA, ~^!FARID" <48860039@inmatemessage.com> 8/13/2021 6:57 AM >>>
To: Mr. Davis
Inmate Work Assignment: UNICOR

FYI:

Overnight, the FDA has signed off a third dose booster for the immunocompromised as detailed in my email. It is all over

the news.

Please advise to my case
-----Provider on 8/13/2021 6:37 AM wrote:

>
The FDA is considering updated guidance. At this point there is no recommendation for a booster. It is expected to come down soon.

>>> ~^!"FATA, ~^!FARID" <48860039@inmatemessage.com> 8/12/2021 7:48 PM >>>
To: Mr. Davis
Inmate Work Assignment: UNICOR

Mr. Davis, NP,

The FDA is authorizing a COVID vaccine booster dose for some immunocompromised individuals.

Those include, cancer patients and transplant patients on immunosuppressive therapy.

In my case, being neutropenic with proven recurrent infections (COVID-19, skin infections, ...etc), should I be considered

to receive a booster shot even if my immunosuppressive condition (which is uncommon) is not mentioned or included in

the FDA recommendations ?

Please advise

1 B Black

Nicole Mims - Re: ***Request to Staff*** FATA, FARID, Reg# 48860039, WIL-A-B

From: WIL-InmateToHealthSvcs
To: ~^!FARID ~^!FATA
Date: 7/21/2021 4:49 PM
Subject: Re: ***Request to Staff*** FATA, FARID, Reg# 48860039, WIL-A-B
BC: Nicole Mims

Will forward this message to Ms. Mims for the correction if needed.

Thanks,

>>> ~^!"FATA, ~^!FARID" <48860039@inmatemessage.com> 7/20/2021 7:12 AM >>>
To: HEALTH SERVICES
Inmate Work Assignment: UNICOR

ATTENTION

Please cut and paste the message indicator below into the subject line; only this indicator can be in the subject line.
a93f8e65-33ff-418b-b511-45a22b327aa8
Your response must come from the departmental mail box. Responses from personal mailboxes WILL NOT be delivered to the inmate.

Inmate Message Below

FYI
-----FATA, FARID on 7/19/2021 1:27 PM wrote:

>

Dear Mrs. Mims,

My COVID-19 immunization profile shows that you signed off the administration of the COVID-19 vaccine in the "left deltoid".

Because of the rash in my left arm, the vaccine was injected in my right deltoid instead.

Please make corrections of the record.

Thank you for your consideration

This is changed!
Thanks Mims

N. Mims, RN
FCI/SCP
WILLIAMSBURG

Farid Fata
#48860-039
FCI Williamsburg
P.O. Box 340
Salters, SC 29590

10/28

Honorable Paul D. Borman
Office Clerk of the Court
Theodore Levin U.S. Court House
231 W. Lafayette BLVd., Room 564
Detroit, MI 48226

URGENT Mail

* TIME SENSITIVE *

LEGAL MAIL

FCI/SCP WILLIAMSBURG
P O BOX 220
SALTERS SC 29590

Date: 10-19-21

The enclosed letter was processed through special mail procedures for forwarding to you. The letter was neither opened nor inspected. If the writer raises a problem over which this facility has jurisdiction, you may wish to return the material for further information or clarification. If the writer encloses correspondence for forwarding to another addressee, please return the enclosure to the above address.

Mail Room